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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,498	01/22/2002	John Barnard Welsh	P0026US20	4754

1095 7590 09/13/2005

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,498

Applicant(s)

WELSH ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 7-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date April 22, 2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: Appendix 1

1. The Amendment filed June 27, 2005 in response to the Office Action of February 24, 2005 is acknowledged and has been entered. Previously pending claims 1-3 have been amended. Claims 1 and 3-6 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following objections are being maintained:

Objection to the Specification drawn to amendment of the specification to reflect the status of the parent application at Section 3, page 6 of the paper mailed February 24, 2005. Applicant argues that since the parent applications are provisional, the status should be readily apparent. The argument has been considered but has not been found persuasive. Applicant is directed to MPEP 1301.04.

Objection to the Specification drawn to hyperlinks and/or other forms of browser-executable code at Section 5, page 8 of the paper mailed February 24, 2005. Applicant argues that he could not find any executable hyperlink or other browser-executable code in the specification and that only non-active URL sites are found in the text of the specification. The argument has been considered but has not been found persuasive because the hyperlinks disclosed in the specification have not been inactivated.

Withdrawal of Claim 2

4. As drawn to the withdrawal of claim 2, Applicant argues that the withdrawal is incorrect because Claim 1 recites detecting a level of expression of at least one gene identified in Table 4 which means the claimed method can detect expression of 1, 2, 3 or more genes. Applicants have elected one species hepsin for examination. Applicant further argues that the practical consequence to

Applicant's species election is that for examination purposes hepsin must be one of the at least one gene. Applicant argues that only claims that do not recite or encompass hepsin can be properly withdrawn from consideration because such claims would not read on the elected species and therefore it is not proper to withdraw the limitation of claim 2 which does not exclude hepsin.

The argument has been considered but has not been found persuasive. In the Restriction requirement mailed October 5, 2004, Examiner specifically stated that "Applicant is required to specify and elect a single gene product or a specific combination of gene products to be analyzed". In Applicant's Response to the restriction requirement Applicant specifically stated "...Applicants hereby make the following election: Group I: Hepsin, detection by assaying for expression of mRNA: localized prostate cancer". Since Applicant elected a single gene product, Hepsin, rather than a combination of gene products, Applicant has specified and elected a single gene product as required and the withdrawal of claim 2 drawn to least two genes is proper for the reasons of record.

New Grounds of Objection

5. The amendment filed June 27, 2005 is objected to under 35 U.S.C. 132 because it appears to introduce new matter into the specification. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which does not appear to be supported by the original disclosure is as follows:

Applicant amends the specification and Table 4 to recite SEQ ID NOs 1-49. Although Applicant meets the requirements of 37 CFR 1.821-1.825, as previously set forth, not only the requirements of 35 CFR 1.821-1.825 need to be satisfied but Examiner required, at page 7 of the previous Action, that Applicant demonstrate

that the amendatory material is the same as that disclosed in the specification. On page 9 of the previous action, Examiner clearly stated that sequences corresponding to accession numbers can be modified, changed, and/or updated and thus the cited sequence may vary or change over time. Applicant has not presented objective evidence demonstrating that the accession number sequences submitted are the same as those of the accession numbers originally filed. In the absence of this objective evidence it cannot be conclusively determined whether or not the amendment of the specification and the claims is new matter and it will be assumed for examination purposes that at least some of the accession number sequences have varied or changed over time. Applicant is required to cancel the new matter in the response to this Office action or present objective evidence demonstrating that the newly amended claims are drawn to accession number sequences which are the same as that of the accession numbers originally filed.

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. Claims 1 and 3-6 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a SEQ ID NOS. 1-49 claimed in Claims 1 and 3-6 has no clear support in the specification and the claims as originally filed. A review of the specification as originally filed reveals that there are no sequences associated with the accession numbers disclosed in Table 4. Although Applicant has met the requirements of 37 CFR 1.821-1.825, as previously set forth, not only the requirements of 35 CFR 1.821-1.825 need to be satisfied but Examiner required, at page 7 of the previous Action, that Applicant demonstrate that the amendatory material is the same as that disclosed in the specification. On page 9 of the

previous action, Examiner clearly stated that sequences corresponding to accession numbers can be modified, changed, and/or updated and thus the cited sequence may vary or change over time. Applicant has not presented objective evidence demonstrating that the accession number sequences submitted are the same as those of the accession numbers originally filed. In the absence of this objective evidence it cannot be conclusively determined whether or not the amendment of the claims is new matter and it will be assumed for examination purposes that at least some of the accession number sequences have varied or changed over time. The subject matter claimed in claims 1 and 3-6 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1 and 3-6 are rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,518,028.

The claims are drawn to a method for screening a subject for a prostate disorder, comprising detecting the level of expression of SEQ ID NO:1 in a sample of prostate tissue, comparing to a normal control, wherein a greater expression level in the subject sample compared to the sample from normal control is indicative of the subject having a prostate disorder (claims 1 and 3), wherein the

prostate disorder includes localized prostate cancer, (claim 4), detecting mRNA (claim 5), by Northern blot (claim 6).

US Patent No. 6,518,028 is drawn to a method for early diagnosis of prostate cancer (see title and abstract). Given this information, one would immediately envision screening of localized tumor tissue. US Patent No. 6,518,028 claims a method for detecting malignant prostate hyperplasia in a biological sample comprising isolated mRNA from said sample, detecting hepsin mRNA in said sample, wherein over-expression of said hepsin mRNA compared to normal tissue sample is indicative of the presence of malignant prostate hyperplasia (claim 1) wherein said sample is selected from the group including tumor tissue biopsy (claim 4). US Patent No. 6,518,028 further teaches methods of detection wherein the detection probe comprises 100% of SEQ ID NO:188 (col 13, lines 52-61) which is 1783 nucleotides long and is 100% identical to SEQ ID NO:1 from nucleotides 189-1783 (see Sequence Search us-10-054-498-1.rge Result 7, Appendix 1). It would be expected that this probe would hybridize to and detect overexpression of SEQ ID NO:1 under any stringent conditions of hybridization. The reference further teaches that the probe is useful for detecting expression of hepsin in a cell by a method including the steps of (a) contacting mRNA obtained from the cell with a labeled hepsin hybridization probe; and (b) detecting hybridization of the probe with the mRNA (col 13, lines 58-62). The reference specifically teaches that for mRNA, the analyzing step may be accomplished using Northern Blot analysis to detect the presence of malignant hyperplasia markers in the amplification product. Northern Blot analysis is known in the art (col 6, lines 2-5). Although the reference does not specifically teach the detection of SEQ ID NO:1, the claimed method appears to be the same as the prior art method, absent a

showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the method of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is different from that taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

9. No claims allowed.


10. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

\ A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.



Susan Ungar
Primary Patent Examiner
August 24, 2005

Dp	756	TTGGGACCGGATGACCGGTGGCAAGTCAAGCTTTCGCTAATGATGGAGCAACACTCTGTGGGGGA	815
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AR280046 LOCUS AR280046 1783 bp DNA linear PAT 10-APR-2001

DEFINITION Sequence 188 from patent US 6518028.

ACCESSION AR280046

VERSION AR280046.1 GI:29715235

KEYWORDS

SOURCE

ORGANISM Unknown.

REFERENCE Unclassified.

AUTHORS 1 (bases 1 to 1783)

TITLE O'Brien, J.L.

JOURNAL Methods for the early diagnosis of ovarian and prostate cancer

FEATURES

source Patent: US 6518028-A 188 11-FEB-2003; Location/Qualifiers

1..1783

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ORIGIN

Query Match 67.4% Score 1593.6; DB 6; Length 1783;

Best Local Similarity 99.1%; Pred. No. 2.4e-295;

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Db 216 GCCAGGGAATCATTTAAACAAGAGCAGTGAATGAGCGAGAAAGAGGGTGGCCGACTGTG 275

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QY 916 GCCATCGGGGCGGCAATCTTGCGGCATATGTGCTGTTCTCTCAGAGTGAACAGAGCCG 975

Db 336 GCCATCGGGGCGGCAATCTTGCGGCATATGTGCTGTTCTCTCAGAGTGAACAGAGCCG 395

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Appendix 1, p. 2

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 SOURCE Homo sapiens (human)
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;

REFERENCE
 1 Medison, R.L., Ong, B.O. and Yeh, J.C.
 Nucleic acid molecules encoding transmembrane serine proteases, the
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 ORIGIN
 Query Match 67.4%; Score 1593.6; DB 6; Length 1783;
 Best Local Similarity 99.1%; Pred. No. 2.4e-25;
 Matches 1613; Conservative 0; Mismatches 14; Indels 1; Gaps 1;